Remarks

Claims 27-31, 33-36, 44, 45, and 47-48 were rejected under 35 U.S.C. 102(a) as being anticipated by the Koester article "Koester" (Appl. Opt Vol. 19, No. 11, 1980). Applicants have amended Claim 27 to include the subject matter to Claims 28 and 29, and Claims 28 and 29 are cancelled without prejudice. Thus, no additional search is required for entry of this Amendment. Claim 27 describes a housing capable of being handheld which is not disclosed by Koester. This is supported by page 3 of the Office Action dated October 11, 2001 where the Examiner stated "Koester... does not specifically describe if the instrument is handheld". The Examiner then combined Koester with Zavislan et al. U.S. Patent No. 5,788,639, which shows a handheld housing, to make a rejection under 35 U.S.C. 103(a). The Zavislan et al. patent is one of the parent patents to the present continuation application, and was thus not proper prior art. The Examiner's position had supported the view that Koester by itself does not anticipate or make obvious the claimed invention in a handheld housing. As such, the present rejection for anticipation based on Koester is not well taken as the Examiner has now taken the opposite position on the same reference over two years latter.

The Examiner bases the anticipation rejection on the grounds that "Koester is designed to be placed on the corneal tissue of the eye" and thus "such a device is small enough to be a handheld unit" (page 3 of the Office Action dated April 15, 2004). However, Koester use of its instrument is not sufficient to anticipate that such instrument is small enough to be handheld. If this were true, then any instrument that is used with the eye could be handheld, regardless of the size or weight of the instrument. Applicants enclose with this Amendment a Declaration by James Zavislan, an inventor of the above identified application in which he personally observed at the Columbia Presbyterian Medical Center the instrument described by Koester in this article. The Declaration includes a picture of an instrument of the same design as used by Dr. Koester in his 1980 Applied Optics paper, such picture was provided to Dr. Zavislan by Dr. Koester. Zavislan states that the specular microscope instrument was integrated in an examination table where the patient placed their chin and forehead onto restraints, identical to those found in a slit lamp, and the clinician moved the instrument by a series

of translation controls. Clearly, such an instrument cannot be handheld as contended by the Examiner.

Moreover, Koester discusses the development of a wide-field specular microscope to image corneal endothelium (page 1749 of Koester). As Koester describes in his introduction, this instrument is an evolution of the traditional slit lamp used in ophthalmological examination. It is well known that a slit lamp is a biomicroscope where the patient places their chin in a chin cup and rests their forehead against a strap. The patient is asked to relax and allow their head to rest securely against the chin and forehead rest so to prevent movement of their head. During the examination, a substantial portion of the weight of the patients head is born by the chin rest and significant force is applied to the forehead band. The medical professional moves the illuminator and microscope in various positions to observe the various structures necessary to complete the examination. The medical professional adjusts the position of the microscope relative to the eye by various translation controls. Slit lamps are mounted on fixed platforms because of the need to both support and stabilize the patient's head as well as provide fine control of the instrument by the medical professional.

It is readily apparent by its intended use that the Koester specular microscope cannot be hand-held, as it is simply too large. Furthermore, the design of the Koester microscope teaches away from its use as a hand-held instrument. Koester states that the instrument can operate both in a contact as well as a non-contact mode, and Koester asserts that there are advantages to both non-contact as well as contact imaging. Furthermore, Koester states that "the change from contact to noncontact (imaging) can be as simple as changing objectives" (sentence bridging pages 1754-1755 of Koester). In order to image both in a contact as well as a non-contact mode with cellular resolution, the patient and the instrument must be stabilized in some other way than a pressure contacting relationship between the tissue and imaging window. In the non-contact imaging mode, there is no pressure contacting relationship between the tissue being imaged and the imaging instrument. As mentioned above, the patient-instrument relationship is held by the slit lamp chin/forehead rests and the slit lamp translation controls. Thus, in the non-contact imaging mode the instrument is not intended to be hand-held.

In the contact mode, there is the possibility of trauma (page 1754, column 1, of Koester), which indicates that the relationship between the patient and the instrument must be carefully controlled during contact imaging. In a related enclosed paper by Koester et. al., "Wide Field Specular Microscopy: Clinical and Research Applications", Ophthalmology, vol. 87, no. 9, 1980, pages 849-860, Koester further discusses issues of contact imaging. On pages 851-852 of the Ophthalmology paper Koester again describes the specular microscope as having contact and non-contact imaging. Koester states that the contact mode has the disadvantage of creating folds in Descemet's membrane. On page 854 he states that the non-contact imaging shows less folds than contact imaging and that contact pressure through the dipping cone must be reduced to provide for a "fold-free field."

Given the size of the instrument, the relationship and force of the patient against the instrument, and the desire to have the system provide both non-contact and contact imaging mode, there is no reason to make Koester's instrument hand-held. As a contact imaging system it is only intended to image the cornea, a tissue that is in nominally the same place for everyone. Thus, there is no need for the flexibility of a hand-held instrument. At most only two sites are imaged, both sites are corneas, and these can be imaged with the patient in one position with the microscope translated from one eye to the other. The uniformity of anatomical location and the delicate nature of the eye do not suggest that the Koester instrument be hand-held.

Thus, Applicants respectfully submit that Koester does not describe a handheld instrument or an instrument that could be handheld, as contended by the Examiner. Applicants submit that the Examiner is using hindsight learned from the present application, which is prohibited. It is further evident from the Declaration of Dr. Zavislan, that in fact, the instrument in Koester is not handheld nor could be handheld as it is too large, unlike the present invention. Accordingly, Koester does not anticipate Claims 27, 34, 47 or their respective dependent claim, and withdrawal of this rejection of Claims 27-31, 33-36, 44, 45, and 47-48 is requested.

Claims 27-31, 44, and 47-48 were rejected under 35 U.S.C. 102(a) as being anticipated by Maurice article (Experientia, Vol. 24, pp. 1094-1095, 1968). A patent claim is anticipated only if each and every element of the claim is present in a single prior

art reference. Union Oil Co. of California v. Atlantic Richfield Co., 208 F.3d 989 (Fed. Cir. 2000). Claim 27 describes a housing capable of being handheld. No figure or description suggests that Maurice's specular microscope for imaging the eye has a handheld housing, and thus Maurice cannot anticipation Claims 27 or 47. FIG. 1 of Maurice is described on page 1749 of Koester. Applicants believe that Maurice describes a scanning slit microscope for examination of the eye, and it is well known that such microscopes are not handheld but adapted into a table configuration, such as described earlier and in the Declaration of Dr. Zavislan. Clearly, Maurice's FIG. 1 illustration of the end of its instrument is not sufficient to support that the entire instrument is of a size and weight that can be handheld. Thus, Applicants respectfully request that the Maurice anticipation rejection of Claims 27 and 47 and of their respective dependent claims be withdrawn.

Claims 27, 28, 30, 31, 44, 45, and 47-48 were rejected under 35 U.S.C. 102(a) as being anticipated by Ishihara et al., EP 0 683 386 A1 ("Ishihara"). Ishihara is limited to producing an area illuminated image, and thus fails to describe light representing a section. Imaging a volume of tissue is not comparable to imaging a section. Thus, no anticipation of Claim 27 can be present. Claim 45 depends on Claim 34, which for similar reasons is not anticipated by Ishihara. Claim 47 has been amended similar to Claim 27, and thus also is not anticipated by Ishihara. Thus, withdrawal of the rejection of Claims 27, 45, and 47 and of their respective dependent Claims 30-31, 44, and 48, is requested.

Claims 27, 28, 30, 31, 44, 45, and 47-48 were rejected under 35 U.S.C. 102(a) as being anticipated by Maekawa et al., JP 8-140961, ("Maekawa"). This Japanese Patent Application corresponds to U.S. Patent No. 5,722,398 ("Maekawa '398"), as determined by the European Patent Office database at "espacenet.com". A copy of Maekawa '398 is enclosed for your convenience. Accordingly, Applicants have used Maekawa '398 for purposes of English translation. Maekawa is similar to Ishihara as evident from use of the same probe 58. Maekawa, like Ishihara, images a volume of tissue, and thus fails to describe light representing a section. Imaging a volume of tissue is not comparable to imaging a section. Thus, Claims 27, 30, 31, 44, 45, and 47-48 are not anticipated by Maekawa, and withdrawal of their rejection is requested.

Claims 27-36, 44, 45, 47, and 48 were rejected under 35 U.S.C. 102(b) as being anticipated by Harris, U.S. Patent No. 5,120,953. Claim 27 describes a window having a surface capable of being pressed into a contact relationship with the surface of a tissue sample, and an illumination beam which is focused by an objective lens through the window to the tissue sample. It is the Examiner's position that the objective lens 110 of FIG. 10 of Harris operates as the claimed window (page 6 of the Office Action dated April 15, 2004). However, Claim 27 has both an objective lens and a window, thus if objective lens 110 operates as the claimed window, then Harris clearly lacks another objective lens for focusing illumination through the lens 110 to the tissue sample, where the only optic present providing such focusing is lens 110. Moreover, although not described in Harris, Applicants believe that objective lens 110 must be movable to change focus in the FIG. 10 system, since actuator 102 has no capability to move the location of the focused illumination relative to the imaged tooth 107. It is obvious to one skilled in the art that lens 110 cannot act as a window in a pressure contacting relationship where it must be able to move to locate the illumination focus on or inside the tooth to form an image. Accordingly, Harris does not anticipate Claims 27, 34, and 47, along with their respective rejected dependent claims, and withdrawal of the Harris anticipation rejection is requested.

Claims 37-43 and 46 were rejected under 35 U.S.C. 103(a) and being unpatentable over Maekawa in view of Hochman et al., U.S. Patent No. 5,699,798 ("Hochman"). Claim 37 describes imaging the tissue through an objective lens to provide at least one image of a section of the tissue. Maekawa relies on volume-based imaging and thus fails to describe light representing a section. Hochman has no capability to provide a sectional image, and thus does not describes that which is absent in Maekawa. Thus, neither Maekawa, nor Hochman, either alone or in combination describes or suggests Claims 37, and withdrawal of the 35 U.S.C. 103(a) rejection of Claim 37 along with its dependent Claims 38-43 and 46 is requested.

It is believed the Application is in condition for allowance. If a notice of allowance is not forthcoming, entry of this Amendment for purpose of Appeal is requested. A Petition for a three-month extension of time with the required fee is enclosed.

Respectfully submitted,

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Kenneth J. LuKacher
Attorney for Applicant(s)
Registration No. 38,539

South Winton Court
3136 Winton Road South, Suite 204
Rochester, New York 14623
Telephone: (585) 424-2670
Facsimile: (585) 424-6196

Enclosures: 2 Certificates of Mailing by Express Mail, Express Mail No. EV325177007US;
Combined Amendment Transmittal and Petition for Extension of Time
with check for $490.00;
Declaration of James M. Zavislan;
Article by Koester et al. entitled "Wide Field Specular Microscopy"; and
Copy of U.S. Patent No. 5,722,398.